K130790

510(k) SUMMARY

Phonak's Lyric2

JUN 2 7 2013

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Phonak LLC
4520 Weaver Pkwy
Warrenville, IL 60555

Phone: 630-821-5058
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Contact Person: Laura Ellman

Date Prepared: May 29, 2013

Name of Device and Name/Address of Sponsor:

Lyric2

Phonak LLC
4520 Weaver Pkwy
Warrenville, IL 60555

Common or Usual Name: Lyric or Lyric2

Classification Name: Hearing Aid, air conduction

Predicate Devices

	MANUFACTURER'S NAME	DEVICE'S TRADE NAME	510(K) NUMBER
1	Insound Medical, Inc.	Insound XT Series	K021867
2	Insound Medical, Inc.	Lyric Hearing Aid	K081136

Intended Use / Indications for Use

The Lyric 2 hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an appropriately trained ENT Physician, Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. Upon device removal the hearing aid is discarded.

Technological Characteristics

Lyric2 is a disposable, programmable, deep-canal, extended-wear, air conduction hearing device. It uses an analog, digitally programmable WDRC ("Wide Dynamic Range Compression") circuit with very low power consumption. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The amplification characteristics are contained in digitally programmable memory, and adjustment of device parameters is achieved through the proprietary Fitting System and Software.

The Lyric2 consists of:

- A programmable application specific integrated circuit ("ASIC") for analog signal processing. An analog microphone receives sound waves that will be amplified and transmitted to the speaker.
- A custom made built-in battery to power the amplification circuit.
- A magnetic sensor to program device parameters and to remotely control user settings (On/Off/Sleep/Volume).
- Mechanical components to protect the device from cerumen.
- A removal loop to allow the user and/or professional to remove the device.
- Seals that allow the device to fit comfortably in the ear canal

Accessories available for Lyric2:

- User Remote Control
- Device sizer to determine best device size
- Length sizer to determine insertion depth
- An insertion tool for insertion and removal of device and device sizers
- A dedicated software and programming interface to program the device with customer specific settings

Performance Data

The performance characteristics of the Lyric Hearing Aid have been evaluated in accordance with ANSI S3.22:2009, "Specification of Hearing Aid Characteristics." The device met all applicable specifications developed by the company in accordance with design input specifications. Additional performance and functional testing, including biocompatibility testing, electrical safety, and electromagnetic compatibility testing, has confirmed the equivalent performance of the modified Lyric compared to the cleared Lyric. Post-market clinical testing also confirmed the comparable performance of the Lyric2 to the cleared device. These data included an assessment for appropriate device sizing, as well as clinical assessments of gain, speech understanding, and sound quality of the study device, length of device wear, patient ratings of comfort, assessment of the proportion of the otherwise eligible population who meet the sizing parameters of the study device, post-removal health of the ear, and usability evaluations by patients and audiologist. The clinical assessments performed demonstrated the comparable safety and efficacy of the Lyric2.

Substantial Equivalence

The Lyric2 has the same general intended use and same indications, similar technological characteristics, and same principles of operation as the cleared Lyric. The minor differences in the

Lyric2's technological characteristics do not raise new questions of safety or effectiveness. Bench and clinical testing demonstrates that the Lyric2 is as safe and effective as the cleared Lyric. Thus, the Lyric2 is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 27, 2013

Phonak LLC
% John. J. Smith, MD, JD
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K130790
Trade/Device Name: Lyric 2
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing aid, air-conduction
Regulatory Class: Class I
Product Code: ESD
Dated: May 29, 2013
Received: May 29, 2013

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130790

Device Name: Lyric2

Indications for Use:

The hearing aid is a disposable, extended-wear air conduction hearing aid, designed to be used and worn by hearing-impaired persons. Hearing assistance is achieved through amplification of sound pressure waves, which are transmitted to the external ear canal via air conduction. The hearing aid is placed in the ear canal by an appropriately trained ENT Physician, Audiologist or Hearing Aid Dispenser and can remain in the ear canal for up to 4 months or until the battery is depleted. Upon device removal the hearing aid is discarded.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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